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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,468	08/20/2004	Takusaburo Ebina	03725/0201718-US0	8915

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EXAMINER

ISSAC, ROY P

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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09/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,468

Applicant(s)

EBINA ET AL.

Examiner

Roy P. Issac

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/27/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application is a 371 of PCT/JP03/01979 filed 02/24/2003 and claims priority and under 35 U.S.C §119 (a)-(d) and 365(c) to foreign application JAPAN 2002-47021 filed 02/22/2002 and to JAPAN 2002-106632 filed 04/09/2002.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 13, 19 and 25 provides for the use of compositions comprising adsorption fraction obtained from *Tricholoma Matsutake*, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7, 13, 19 and 25 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-12 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating metastatic foci, does not reasonably provide enablement for prevention of metastatic foci. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The invention relates to the use of an adsorption fraction of *Tricholoma matsutake* for the prevention and treatment of metastatic foci.

Art Unit: 1623

The relative skill of those in the art:

The relative skill of those in the art is high, with a typical practitioner having obtained a PhD, M.D. or equivalent advanced degree.

The amount of direction or guidance presented and the presence or absence of working examples:

The specification does not provide any examples of the prevention of any diseases. The specification provides examples of using extracts against metastatic foci. However, the specification does not provide examples of administration of any fractions someone who doesn't have any metastatic foci or tumor showing the prevention tumor or metastatic foci development.

The predictability or lack thereof in the art: the instant claimed invention is highly *unpredictable* as discussed below:

Prevention of metastatic foci is not the same as the treatment of a disease condition. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

Art Unit: 1623

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms?

3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many of the therapies that are useful for treating a disease are not useful preventing the disease. For example, antibiotics, chemotherapeutics and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer. Thus, it is highly unlikely that any of the metastatic foci can be prevented by the administration of the compositions of the instant application.

The quantity of experimentation necessary:

In order to determine whether the claimed method can prevent metastatic foci, one of ordinary skill in the art will need to answer the questions posed above, which will require significant intellectual and financial input, and an effort that will be collaborative

Art Unit: 1623

in nature with clinical physicians, organic chemists and biochemists involved, resulting in enormous burden on one of skill in the art to practice the invention as claimed.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the compositions and methods for the prevention of metastatic foci as claimed, and for the prevention of any disease condition recited in the instant claims.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to practice the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the acronym IAP without defining it first within claims renders the claim indefinite. Where a trademark or trade name or abbreviation is used in a claim as a limitation to identify or describe a particular material

Art Unit: 1623

or product, the claim does not comply with the requirements of 35 U.S.C 112, second paragraph. See *Ex parte Simpson*, 218 USPQ (Bd. App. 1982). The claim scope is uncertain since the abbreviation or trademark or trade name cannot be used to identify any particular material or product. An abbreviation or trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, an abbreviation or trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the abbreviation used herein renders the identification /description indefinite.

Claims 5, 7 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims herein recite the phrase, "functional food". However, the phrase is not clearly defined in the specification and it is not clear what function is performed by the food. As such, one of skill in the art would not be able to ascertain the metes and merits of the claims herein.

Claims 4-5, 10, 16 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim's recitation of the phrase "optionally" renders the claims indefinite, since "optionally" renders uncertain and unclear as to whether the other ingredients will be part of the claimed composition.

Claims 1-6, 8-12, 14-18 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recite the phrase, "hot

Art Unit: 1623

water" which does not clearly convey to one of skill in the art the temperature range encompassed by the phrase. As such, one of skill in the art would not be able to ascertain the metes and merits of the claims herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-12, 14-18 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsunaga K. (WO 01/49308; EP1,256,351 is used in lieu of translation; PTO-892) in view of Sakakida et. al. (U.S. Patent No. 4,177,108; PTO-892) Matsunaga et. al. discloses a method for producing adsorption fraction of Tricholoma Matsutake with an alkaline solution followed by separation with anion exchange resin. (Abstract, Page 15, claim 2). Matsunaga discloses immune enhancing compositions and health food comprising adsorption fractions from Tricholoma Matsutake. Immune enhancing is expected to increase serum IAP value. Matsutake discloses the use of Tricholoma matsutake extract for the treatment of tumor proliferation. (Page 15, claim 10). Tumor proliferation is considered to include treating metastatic foci. Note that it is well settled that "intended use" of a composition or product, e.g., "immune enhancing health food", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an

Art Unit: 1623

effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, selecting an adsorption fraction with particular protein and carbohydrate content and determining the protein and carbohydrate content of various fractions is considered well within the basic skills of one of ordinary skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Matsunaga et. al. does not expressly disclose the particular strain FERM BP-7304 or a fraction that contains the particular carbohydrate content or protein content of claim 1 herein.

The '108 patent discloses a strain of *Tricholoma matsutake* that appears to be the same as the reference strain herein because they are of the same genus and species. Both the reference strain and the reference strain are expected to produce the same results intrinsically. Furthermore, since claims herein use the open transitional phrase comprising, the inclusion an extraction fraction is expected to contain the adsorption fraction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an adsorption fraction of *Tricholoma matsutake* comprising the same carbohydrate and protein content as herein because the genus and species of *Trichlooma matsutake* and the method of extraction using alkaline solution are well known. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in

Art Unit: 1623

their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Therefore, one of ordinary skill in the art would have reasonably expected that the *Tricholoma matsutake* of '108 would have resulted in substantially similar or better adsorption fraction with substantially similar effects.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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